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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,557	GLENSBJERG, MARTIN	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *130-178* is/are pending in the application.

4a) Of the above claim(s) *130-162* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *163-178* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 13 October 2004 is acknowledged and has been entered. Due to the amendments to the drawings, specification, and claims, the objections and rejections based on 35 USC § 112 made in the previous Office Action have been withdrawn.

2. On 14 April 2004, a provisional election was made with traverse to prosecute the invention of Group II, claims 163-173. In the previous Office Action, Applicant was reminded to affirm the election in replying to the Office Action. However, in the Response filed 13 October 2004, Applicant did not provide reasons for traversing the restriction requirement. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 168 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 168, line 4, the phrase "out of the device" is vague and confusing. Since there is no sample outlet, as recited in the parent claim (claim 163, line 20), it is confusing as to how the "flow system" (line 2) can comprise means for regulating flow (line 3) out of the device.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 163-165, 167-169, 171, and 173-178 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilding et al (US 5,726, 026).

In the instant claims, Wilding et al teach a device adapted to be used in a system for the assessment of at least one parameter of particles in a liquid analyte material, the device comprising a sample compartment comprising an exposing domain, said exposing domain allowing electromagnetic signals from a sample in the exposing domain to pass to a detection device, an inlet through which a volume of a liquid sample representing the analyte material can be introduced, a flow system comprising at least a

channel allowing at least a portion of the volume of the liquid sample to flow within the device, means for arranging the device in relation to the detection device, the device having no sample outlet, by disclosing a device that includes a detection chamber (column 15, line 28) which has an optical window disposed over the chamber (column 15, line 29), wherein the cholesterol content of a sample may be determined by applying a sample via inlet port 152c, wherein it flows through channel 154d to the tortuous mixing/reaction chamber (column 15, lines 13-18 and Figure 9), wherein the device is held in a nesting site in an appliance for optical detection means (column 15, line 62 to column 16, line 3), and wherein the device can have entry ports 133 on opposite ends of mesoscale flow channels 132a and 132b, and entry port 137 (column 13, lines 37-55; and Figure 8A).

Although Wilding et al reference does not explicitly disclose that the exposing domain allows electromagnetic signals from a sample in the exposing domain to pass to a detection device, the instant reference teaches a device with an optical window disposed over a detection chamber and that detection of sample can be performed by optical detection means, thereby disclosing that the device has the capability of performing the claimed limitation since optical detection means necessarily requires the transfer of electromagnetic signal from a sample to a detection device.

Although Wilding et al reference does not explicitly disclose that the device has no sample outlet, Figure 8A discloses a device that comprises several inlet ports, but no outlet ports, thereby teaching a device without a sample outlet.

In addition, although claim 1 mentions a spatial image representation and a detection device by reciting "and to form, in the detection device, a spatial image representation of the exposing domain processable by processing means of the detection device" (lines 14-17), the spatial image representation, detection device, and processing means of the detection device are not part of the device and the claimed invention since they are outside of the device itself, and therefore not given patentable weight. The above lines referring to the detection device have thus been excluded from the prior art search.

Regarding claim 164, Wilding et al teach that the flow system additionally comprises a flow channel part in which one or more reaction components initially loaded in the flow channel part is added to at least a portion of the volume of the liquid sample representing the analyte material, by disclosing that cholesterol esterase, buffer, and sample are applied to inlet ports 152a, 152b, and 152c, respectively, and that the mixture flows through channel 154d to the tortuous mixing/reaction chamber (column 15, lines 14-18 and Figure 9).

Regarding claim 165, Wilding et al teach at least one of the reaction components is in freeze-dried form, by disclosing that protein binding substances introduced in aqueous solution may be retained in a mesoscale structure in lyophilized form (column 10, lines 57-59).

Regarding claim 167, Wilding et al teach that part of the channel has at least one bend or obstruction resulting in turbulent flow in liquid passing the bend or obstruction,

by disclosing a device where flow channel 179 may include structural elements to promote turbulent flow (column 17, lines 44-45 and Figure 10A).

Regarding claim 168, Wilding et al teach that the flow system comprises one or more means for regulating the velocity of the flow into, within, or out of the device, the velocity regulating means comprising valves, by disclosing a device with valves in the devices that may be utilized to direct fluid flow (column 20, lines 63-67).

Regarding claim 169, Wilding et al teach that the device comprises means for performing filtration, concentration, and magnetic attraction, by disclosing a device that can function as a filter (column 9, line 6), test for the concentration of a molecular or ionic analyte (column 5, lines 31-32), and apply a magnetic field to effect filtration of particulate matter from the test sample using magnetic particles (column 9, lines 29-33).

Regarding claims 171, 173 and 175-177, Wilding et al teach the interior of the sample compartment has an average depth of between 20 μm and 200 μm (171 and 175-176) and that the volume of the sample compartment from which electromagnetic radiation is exposed, is in the range between 0.04 μL and 4 μL (claims 173 and 177), by disclosing that the detection chamber has at least one cross-sectional dimension on the order of 0.1 μm to 1000 μm (column 7, lines 60-61) and that a pre-determined sample volume will ordinarily be on the order of about 1 μL, wherein the pre-determined sample volume is in a metering chamber for analysis (column 16, lines 56-60). Although Wilding et al does not explicitly teach that the metering chamber will be on the order of about 1 μL, it is inherent that the chamber is at least 1 μL since it can hold sample volume of that amount. In addition, since the detection chamber has at least one cross-

sectional dimension on the order of 0.1 μm to 1000 μm, the chamber can have multiple dimensions on the order of 0.1 μm to 1000 μm, which can provide chamber volumes that include 1 μL.

Regarding claim 174, Wilding et al reference teaches that the flow system comprises one or more mixing chambers, by disclosing a central mesoscale mixing/capture/detection chamber 135, as stated above (column 13, lines 37-45; and figure 8A).

Regarding claim 178, Wilding et al reference teaches that the device comprises a propelling means, by disclosing pump 34 to convey sample into a port and then through a flow passage (column 9, lines 58-67; and Figure 4).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 166 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (US 5,726,026) in view of Yager et al (US 5,716,852).

Wilding et al reference has been disclosed above, but fails to teach that part of the channel provides laminar flow in the liquid sample.

Yager et al teach that practically all flow in microstructures is laminar due to extremely small inertial forces in such structures, in order to allow movement of different layers of fluid and particles next to each other in a channel without any mixing other than diffusion (column 3, lines 8-12).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device of Wilding et al, laminar flow of fluid in a channel, as taught by Yager et al, in order to allow movement of different layers of fluid and particles next to each other in a channel without mixing other than diffusion. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in providing laminar flow, as taught by Yager et al, in the device of Wilding et al, since both references teach flow through microstructures.

10. Claim 170 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (US 5,726,026) in view of Masuda et al (US 4,472,498), Ozaki et al (US 5,754,289), Fesik et al (US 5,804,390), and Allen et al (US 5,190,857).

Wilding et al reference has been disclosed above, but fail to disclose one or more compartment(s) or domain which allows spectrophotometric measurement by mid-infrared attenuation, near-infrared attenuation, visible attenuation, ultraviolet attenuation, photoluminescence, raman scatter or nuclear magnetic resonance.

Masuda et al teach a detection layer (column 6, line 15 and Figures 1-6) and spectrophotometry is used as the optical measurement system with ultraviolet rays, infrared rays, and visible rays (column 18, lines 63-68 and column 19, lines 1-2), in order to measure the concentration of a substance which plays an important biochemical role using a protein capable of specifically binding the substance through competitive binding (column 1, lines 8-13).

Ozaki et al teach the use of an FT-Raman spectrophotometer to measure Raman scattering spectra from a cell holder (column 6, lines 11-15), in order to measure a vital substance (column 2, lines 56-57).

Fesik et al teach the use of a nuclear magnetic resonance spectroscopy to follow the changes in chemical shifts of a target molecule upon the addition of ligand compounds, in order to provide a rapid and efficient screening method for identifying ligands that bind to therapeutic target molecules (column 5, lines 38-46).

Allen et al teach the use of photoluminescence spectroscopy, in order to detect low levels of analytes, including particles, cells, and cell fragments (column 2, lines 27-29 and column 3, lines 1-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device of Wilding et al, a method measuring the detection

layer using spectrophotometry with ultraviolet rays, infrared rays, visible rays, Raman scattering spectra, nuclear magnetic resonance, and photoluminescence, as taught by Masuda et al, Ozaki et al, Fesik et al, and Allen et al, respectively, in order to measure the concentration of a substance, measure a vital substance, follow the changes in chemical shifts of a target molecule, and detect low levels of analytes, respectively. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including the specific spectrophotometric measurements taught by Masuda et al, Ozaki et al, Fesik et al, and Allen et al, in the device of Wilding et al, since Wilding et al teach that spectroscopy can be used to detect analytes (column 18, lines 6-7), and the specific spectrophotometric measurements of Masuda et al, Ozaki et al, Fesik et al, and Allen et al are alternative techniques of different types of measurements using spectrocopy.

11. Claim 172 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al (US 5,726,026) in view of Kricka et al (US 5,744,366).

Wilding et al reference is disclosed above and additionally teaches that a sample compartment has dimensions in a plane parallel to an exposing window, by disclosing that detection region 128 is covered by glass window 109 (column 12, lines 51-52; column 13, lines 21-22; and Figure 6B), but fail to disclose that the dimensions are in the range between 1mm by 1mm and 10 mm by 10 mm.

Kricka et al teach a device with chambers or flow channels generally having widths and lengths on the order of 1 mm or larger wherein the chamber is fabricated in

a substrate and a cover is disposed over the substrate (column 8, line 67 to column 9, line 12), in order to allow adequate cell movement within the chamber (column 8, lines 59-65).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device of Wilding et al, a device with chambers generally having widths and lengths on the order of 1 mm or larger, wherein the chamber is fabricated in a substrate and a cover is disposed over the substrate, as taught by Kricka et al, in order to allow adequate cell movement within the chamber. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including chambers with dimensions have widths and lengths on the order of 1mm or larger, as taught by Kricka et al, in the device of Wilding et al, since both Kricka et al and Wilding et al teach microfluidic devices with covers.

Response to Arguments

12. Applicant's arguments filed 13 October 2004 have been fully considered but they are not persuasive.

13. Applicant argues on page 12, lines 14-15 that Wilding et al reference does "not teach devices without a sample outlet".

Applicant's arguments are not persuasive because Wilding et al teach a device that can have entry ports 133 on opposite ends of mesoscale flow channels 132a and

132b, entry port 137, and a mesoscale mixing/capture/detection chamber 135 (column 13, lines 37-55; and Figure 8A). There is no indication of a sample outlet. Although the instant reference discloses sample outlet ports in embodiments that are different from the device in Figure 8A, the sample outlet ports are clearly stated and indicated in the drawings. For example, the specification at column 8, lines 48-52 state that device 10 has outlet port 16, wherein the outlet port 16 is clearly shown in Figure 1. Since Figure 8A clearly marks every embodiment of the device as an inlet, channel, or chamber, and does not indicate an outlet, Wilding et al reference provides adequate teaching of a device without a sample outlet and therefore clearly anticipates the claimed invention.

14. Applicant argues on page 13, lines 11-13 that "Applicant disagrees that Wilding "inherently anticipates" the disengaging limitation claimed in the present invention". Although Applicant has failed to provide reasons for the traversal, this point is moot since the claims have been amended to remove the instant limitation from the claimed invention.

15. Applicant argues on page 13, lines 19-20 that Wilding et al reference "describes a unit used for biological assays that measure binding" and argues on page 13, lines 24-27 that "The present invention, however, does not measure binding and does not contain binding substrates. Therefore this embodiment does not anticipate the present invention".

In response to applicant's argument that Wilding et al reference does not anticipate the present invention because the reference describes a unit that measures binding and the present invention does not measure binding, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

16. Applicant argues that Yager et al, does "not teach devices without sample outlet" (page 15, lines 8-10), that "the combination of Wilding et al in view of Yager et al does not teach each and every element of the claimed invention" (page 15, lines 14-18), and that "the outlet is an essential feature of the Wilding device" and "Yager et al teaches the analysis of sample streams, which also clearly requires an outlet" (page 15, line 20 to page 16, line 5).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Wilding et al reference teaches a device without sample outlet, as stated above, and Yager et al reference is applied for limitations in claim 166 that are not recited in

claim 163. In addition, since Wilding et al reference teaches flow channels in a device that does not have an outlet (Figure 8A), the flow in Yager et al would function in the device of Wilding et al. Therefore, the combination of Wilding et al and Yager et al is obvious over the claimed invention.

17. Applicant argues that "there would have been no motivation for one of skill in the art to modify the devices taught in Wilding and Yager so as to remove the sample outlet, because the devices in both references are used in fundamentally different methods", that both "Wilding et al and Yager et al are intended to measure sample coming from flowing streams of analyte", and that "one of skill in the art would not look to Wilding to Yager to design an analytical device where the device stops the analyte stream" (page 16, lines 6-19).

Applicant's arguments are not persuasive because Applicant has not appropriately traversed the combination of Wilding et al and Yager et al. Applicant argues that *both* Wilding et al and Yager et al references have the fundamentally different method of measuring flowing sample while the instant invention stops the analyte stream. However, Applicant has not provided reasons why it would not be obvious to combine Wilding et al in view of Yager et al for the limitations of claim 166.

In addition, Applicant's arguments are not persuasive because Wilding et al reference clearly provides flow channels on either side of the detection chamber (Figure 8A), which indicates the capability of flow to be conducted to and from the chamber, even in the absence of a sample outlet.

18. Applicant argues that the combination of Wilding et al in view of Masuda et al, Ozaki et al, Fesik et al, and Allen et al "do not teach each and every element of the claimed invention" since Masuda et al, Ozaki et al, Fesik et al, and Allen et al "do not teach devices without sample outlet" (page 17, line 8-18).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Since Wilding et al reference teaches a device without sample outlet, as stated above, and Masuda et al, Ozaki et al, Fesik et al, and Allen et al references are applied to limitations in claim 170 that are not recited in claim 163 with proper motivation. Therefore, Wilding et al in view of Masuda et al, Ozaki et al, Fesik et al, and Allen et al are obvious over the claimed invention.

19. Applicant argues that the combination of Wilding et al in view of Kricka et al "does not teach each and every element of the claimed invention" (page 19, lines 7-13) since Kricka et al "do not teach devices without sample outlet" (page 18, line 9-10). Applicant also recites teaching in Kricka et al wherein in "an alternative embodiment, the target chamber may be omitted, by should be replaced with a port, disposed anywhere over the flow system, to facilitate filling or evacuating the device" (page 18, lines 13-16). In addition, Applicant argues that "removal of the outlet from any of the devices

disclosed in these three documents would render them unsuitable for the uses disclosed in the documents" (page 18, lines 20-22).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Wilding et al reference teaches a device without sample outlet, as stated above, and Kricka et al references are applied for limitations in claim 172 that are not recited in claim 163.

In addition, Applicant's arguments are not persuasive because Kricka et al reference is applied to the limitation of chamber dimensions, not for a device without an outlet, which has already been taught by Wilding et al, as stated above. However, the chamber dimensions would work in the device of Wilding et al since both references teach mesoscale and microfluidic devices, including detection chambers therein. Since Wilding et al reference has taught a device without sample outlet, and the proper motivation of detecting cells has been provided for combining Wilding et al and Kricka et al references, Wilding et al in view of Kricka et al are obvious over the claimed invention.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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